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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

BEVERLY WATSON,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CASE NO.: 2:17-cv-00210-JHE**
	)	
C.R. BARD, INC. and BARD ACCESS SYSTEMS, INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

COMES NOW Plaintiff, Beverly Watson, by and through her undersigned counsel, and brings this Complaint against C.R. Bard, Inc. and Bard Access Systems, Inc. (hereinafter referred to collectively as "Defendants"), and alleges as follows:

1. This is an action for damages relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective device sold under the trade name of BardPort® Implanted Port with Groshong© Catheter (hereinafter "BardPort", or "Defective Device").

PARTIES

2. Plaintiff, Beverly Watson, is an adult resident of Shelby County, Alabama, and claims damages as set forth below.

3. Defendant C.R. Bard, In. ("Bard") is a New Jersey corporation with its principal place of business located in Murray Hill, New Jersey. Bard is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and

introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the BardPort.

4. Defendant Bard Access Systems, Inc. ("BAS") is a Utah corporation with its principal place of business located in Salt Lake City, Utah. BAS conducts business throughout the United States, including the State of Alabama, and is a wholly owned subsidiary of C.R. Bard. BAS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the BardPort.

JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to 28 U.S.C. §1332(a) based upon the complete diversity of the parties. The amount in controversy exceeds, exclusive of interest and costs, the sum of $75,000.00.

6. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred within this judicial district. Defendants conduct business in this judicial district to include, but not limited to, the sale of the BardPort.

GENERAL FACTUAL ALLEGATIONS

7. The BardPort® Implanted Port with Groshong© Catheter ("BardPort") is one of dozens of varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants for decades.

8. According to the BAS Instructions For Use, BardPorts "are totally implantable vascular access devices designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products."

9. The BardPort is a medical device which is used to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin.

10. The BardPort is a system consisting of two primary components: an injection port and a silicone catheter.

11. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube called a catheter that is inserted into a blood vessel.

12. The BardPort is "indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples."

13. According to BAS marketing materials, "more BardPorts are placed worldwide than any other port."

14. According to BAS marketing materials, the Groshong© Catheter "[s]ilicone material offers superior biocompatibility and thromboresistance to improve indwelling catheter time."

15. When used as part of the BardPort system, the length of the Groshong© Catheter is 50 centimeters.

16. The BardPort is commonly used in patients with cancer to facilitate the administration of chemotherapy and/or radiation treatment.

17. According to BAS's Patient Information (available on their website, bardaccess.com—last accessed February 7, 2017), "the port is made from special medical grade materials designed for safe long-term use in the human body."

18. According to BAS's Patient Information (available on their website, bardaccess.com—last accessed February 7, 2017), the BardPort can be left implanted in the patient indefinitely.

19. Defendants obtained "clearance" to market these products under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

20. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacture can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the produce involved is safe and effective.

21. In *Medtronic, Inc.* v. Lohr, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996).

22. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

23. At all times relevant, Defendants misrepresented the safety of the BardPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the BardPort system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

24. At all times relevant to this action, Defendants knew and had reason to know, that the BardPort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

25. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with BardPorts had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs.

26. Soon after the BardPort was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the BardPort was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that BardPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage;

b. cardiac/pericardial tamponade;

c. cardiac arrhythmia and other symptoms similar to myocardial infarction;

d. severe and persistent pain;

e. and perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

27. Defendants were aware or should have been aware that the BardPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

28. Defendants also intentionally concealed the severity of complications caused by the BardPort and the likelihood of these events occurring.

29. Rather than alter the design of the BardPort to make it safer or adequately warn physicians of the dangers associated with the BardPort, Defendants continued to actively and aggressively market the BardPort as safe, despite their knowledge of numerous reports of catheter fracture and associated injuries.

30. Moreover, Defendants' warnings suggested that fracture of the device could only occur if the physician incorrectly placed the device such that "compression or pinch-off" was allowed to occur. In reality, however, Defendants knew internally these devices were fracture and causing serious injuries due to defects in the design, manufacturing and lack of adequate warnings.

31. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the BardPort System, yet consciously failed to act reasonably to:

a. Adequately Inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the BardPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO BEVERLY WATSON

32. Plaintiff Beverly Watson was originally diagnosed with breast cancer in 2006. She underwent extensive treatment at that time and was given a positive prognosis.

33. Plaintiff was diagnosed with breast cancer a second time in 2009. Plaintiff's treating oncologists recommended she undergo chemotherapy and/or radiation treatments that would require the implantation of a port/catheter system to administer the medications.

34. On or about February 24, 2009, the BardPort was implanted in Plaintiff at Shelby Baptist Medical Center, in Alabaster, Alabama, by Dr. Rex A. Sherer.

35. The Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the BardPort that was implanted in Plaintiff.

36. Plaintiff underwent the necessary chemotherapy and/or radiation treatments, and her breast cancer ultimately went into remission.

37. On February 9, 2015, Plaintiff underwent surgery to remove the BardPort at Shelby Baptist Medical Center, in Alabaster, Alabama, by Dr. Clement P. Cotter, Jr.

38. During the procedure, about seven (7) centimeters of the tip of the BardPort catheter were found to have fractured and embolized to Plaintiff's right pulmonary artery.

39. On or about February 10, 2015, Plaintiff was required to undergo another surgery at Shelby Baptist Medical Center, in Alabaster, Alabama, by Dr. Steven Taylor in an attempt to retrieve the fractured catheter tip.

40. This second retrieval surgery was unsuccessful and the foreign material remains lodged inside of Plaintiff pulmonary artery. Plaintiff is now exposed to a lifetime of having a retained foreign body in her pulmonary artery that could cause serious injury, including death, at any time.

41. Due to the defective device, Plaintiff suffered substantial damages including, but not limited to, pain and suffering and economic loss associated with undergoing an otherwise unnecessary surgery. She also continues to suffer pain and suffering as well as economic loss due to the fractured medical device now permanently lodged in her pulmonary artery.

42. Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the risk of catheter fracture or embolization associated with the BardPort. For example, Defendants did not adequately warn of the ways in which device fracture could occur, the likelihood that fracture and embolization could occur, and the know severity of complications when such failures did occur.

43. Plaintiff's physicians relied upon the representations and advertisements to Plaintiff's detriment. Plaintiff's physicians would not have used a BardPort if they had been adequately informed of the dangers and risks associated with doing so.

44. As a result of the failure of the Defendants' BardPort and the Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of the Defendants' acts, omissions and misrepresentations.

45. As a result of the Defendants' actions and inactions, Plaintiff was injured due to the use of the BardPort, which has caused and will continue to cause Plaintiff's various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

CAUSES OF ACTION

COUNT ONE
Alabama Extended Manufacturer's Liability Doctrine ("AEMLD")

46. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

47. Defendants are liable to the Plaintiff for the damages sustained based on the AEMLD as the Defendants manufactured, designed, and/or sold the BardPort, a defective device, which, because of its unreasonably unsafe condition, injured the Plaintiff when such product, substantially unaltered, was put to its intended use. Furthermore, Defendants failed to adequately warn the Plaintiff of the unreasonably dangerous nature of this Defective Device.

48. As a direct and proximate result of the Defendants' defective design, manufacturing defect, and/or Defendants' failure to warn of the BardPort's dangers, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

COUNT TWO
NEGLIGENCE AND WANTONNESS

49. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

50. At all times relevant to this cause of action, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the BardPort.

51. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the BardPort that was implanted in Decedent.

52. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the BardPort so as to avoid exposing others to foreseeable risks of harm.

53. Defendants knew or reasonably should have known that the BardPort was unreasonably dangerous or was likely to be unreasonably dangerous when used in its intended or reasonably foreseeable manner.

54. At the time of manufacture and sale of the BardPort, Defendants knew or should have known that the BardPort:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device;

c. Was designed and manufactured so as to present a unreasonable risk of the device perforating the vena cava wall;

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement.

55. At the time of manufacture and sale of the BardPort, Defendants knew or should have known that using the BardPort in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the BardPort; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

56. Defendants knew or reasonably should have known that users of the BardPort would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

57. Defendants breached their to duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the BardPort in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

c. Failing to use reasonable care to warn or instruct Plaintiff or her prescribing physicians about the BardPort's substantially dangerous condition or about facts making the product likely to be dangerous;

d. Failing to perform reasonable pre and post-market testing of the BardPort to determine whether or not the product was safe for its intended use;

e. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the BardPort;

f. Advertising, marketing and recommending the use of the BardPort, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected the use of the BardPort;

g. Representing that the BardPort was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

h. Continuing manufacture and sale of the BardPort with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA regulations and policy;

i. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the BardPort so as to avoid the risk of serious harm associated with its use;

j. Failing to establish an adequate quality assurance program used in the manufacturing of the BardPort.

k. Failing to establish and maintain and adequate post-market surveillance program.

58. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

59. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

60. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

COUNT THREE
BREACH OF EXPRESS WARRANTY

61. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

62. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the BardPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

63. The BardPort does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

64. At all relevant times, the BardPort did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

65. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the BardPort.

66. At all relevant times, the BardPort was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

67. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

68. As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

COUNT FOUR
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

69. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

70. At the time Defendants marketed, sold, and distributed the BardPort, Defendants knew of the use for which the product was intended and impliedly warranted the product to be of safe merchantable quality, safe, fit and effective for such use.

71. Defendants knew, or had reason to know, that Plaintiff and her physicians would rely on Defendants' judgment and skill in providing the BardPort for the intended use.

72. Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants as to whether the BardPort was of merchantable quality, safe, fit, and effective for its intended use.

73. Contrary to such implied warranty, the BardPort was not of merchantable quality or safe or fit or effective for its intended use, because the product was, and is, unreasonably dangerous, defective, unfit and ineffective for the ordinary purposes for which the BardPort was used.

74. As direct and proximate result of the breach of implied warranty of merchantability, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

COUNT FIVE
BREACH OF IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE

75. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

76. At the time Defendants marketed, sold, and distributed the BardPort, Defendants knew of the particular purpose for which the product was intended and warranted the product to be of safe merchantable quality, safe, fit and effective for such use.

77. Defendants knew, or had reason to know, that Plaintiff and Plaintiff's physicians would rely on Defendants' judgment and skill in providing the BardPort for that particular use.

78. Plaintiff and her physicians reasonably relied upon the skill and judgment of Defendants as to whether the BardPort was of merchantable quality, safe, fit, and effective for its particular purpose.

79. Contrary to such implied warranty, the BardPort was not of merchantable quality or safe or fit or effective for its particular purpose, because the product was, and is, unreasonably dangerous, defective, unfit and ineffective for the particular purposes for which the BardPort was used.

80. As direct and proximate result of the breach of implied warranty of fitness for particular purpose, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

COUNT SIX
NEGLIGENT MISREPRESENTATION

81. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

82. The Defendants made negligent misrepresentations with respect to the BardPort including, but not limited to, the following particulars:

a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that BardPort has been tested and found to be safe and effective to facilitate the administration or chemotherapy and/or radiation treatments in patients with cancer; and

b. The Defendants represented the BardPort was safer and/or more effective than other port/catheter systems.

83. Defendants did not exercise reasonable care or competence in obtaining or communicating the information to the public regarding the characteristics and qualities of the BardPort.

84. Plaintiff and Plaintiff's physicians did, in fact, reasonably rely upon the representations.

85. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

COUNT SEVEN
FRAUDULENT MISREPRESENTATION

86. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

87. The Defendants made fraudulent misrepresentations with respect to the BardPort in the following particulars:

a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations publications, notice letters, and regulatory submissions that the BardPort had been tested and found to be safe and effective to facilitate the administration or chemotherapy and/or radiation treatments in patients with cancer; and

b. The Defendants represented the BardPort was safer and/or more effective than other port/catheter systems.

88. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of the BardPort to consumers, including Plaintiff, and the medical community.

89. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

90. The Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of the BardPort.

91. Plaintiff and her physicians did in fact rely upon the representations. In the absence of the Defendants' representations, the BardPort would not be used in medical treatment plans such as the one at issue in this case.

92. The Defendants' fraudulent representations evinced its callous, reckless, willful, and willful indifference to the health, safety, and welfare of consumers, including Plaintiff.

93. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

94. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

COUNT EIGHT
FRAUDULENT CONCEALMENT

95. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

96. Defendants fraudulently concealed information with respect to the BardPort in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the BardPort was safe and fraudulently withheld and concealed information about the substantial risks of using the BardPort; and

b. Defendants represented that the BardPort was safer than other alternative systems and fraudulently concealed information which demonstrated that the BardPort was not safer than alternatives available on the market.

97. The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the BardPort.

98. The concealment of information by the Defendants about the risks of the BardPort was intentional, and the representations made by Defendants were known by Defendants to be false.

99. The concealment of information and the misrepresentations about the BardPort was made by the Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

100. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the BardPort which the Defendants concealed from the public, including Plaintiff and her physicians.

101. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

102. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

COUNT NINE
FRAUDULENT INDUCEMENT AND SUPPRESSION

103. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

104. Defendants misrepresented to the Plaintiff and the health care industry the safety and effectiveness of the BardPort and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of the BardPort.

105. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that the BardPort had defects, dangers, and characteristics that were other than what the Defendants had represented to the Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from the Plaintiff, the health care industry and consuming public that:

c. the BardPort had been tested and found to be safe and effective for use in the administration of chemotherapy and/or radiation treatments; and

d. that the BardPort was safer, in better quality and in character than other alternative systems and fraudulently concealed information which demonstrated that the BardPort was not safer than alternatives available on the market.

106. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

107. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that the Plaintiff and health care industry would rely on them, leading to the use of the BardPort over competing port/catheter systems.

108. At the time of the Defendants' fraudulent suppression, Plaintiff was unaware of the falsity of the statements being made and believed them to be true. Plaintiff had no knowledge of the information concealed and/or suppressed by the Defendants.

109. Plaintiff justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to the Plaintiff's detriment.

110. Defendants had a post-sale duty to warn Plaintiff and the public about the potential risks and complications associated with the BardPort in a timely manner.

111. The misrepresentations and active fraudulent concealment by the Defendants constitutes a continuing tort against the Plaintiff.

112. Defendants made the misrepresentations and actively concealed information about the defects and dangers of the BardPort with the intention and specific desire that Plaintiff's health care professionals and the consuming public would rely on such or the absence of information in selecting the BardPort.

113. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

114. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants as follows:

a. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00);

b. For an award of punitive or exemplary damages against Defendants;

c. For reasonable attorney fees and costs;

d. For pre-judgment interest; and

e. For such further and other relief this Court deems just and equitable.

JURY DEMAND

Plaintiffs herein demand a trial by jury.

Dated: April 28, 2017

Respectfully submitted,

/s/ Troy A. Brenes
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